REMARKS

The Applicants note that all amendments and cancellations of Claims are made without acquiescing to any of the Examiner's arguments or rejections, and solely for the purpose of expediting the patent application process in a manner consistent with the PTO's Patent Business Goals (PBG),[1] and without waiving the right to prosecute the cancelled claims (or similar claims) in the future.

In the Office Action mailed 5/31/07, the Examiner objected to Claims 4-7 as allegedly being of improper dependent form due to failing to further limit the subject matter of a previous claim (Office Action, pg. 2). The Applicants have cancelled Claim 4-7. As such, the objection is moot.

In the Office Action dated 5/31/07, the Examiner rejected Claims 1 and 4-11 under 35 U.S.C. 112, first paragraph, as allegedly lacking enablement (Office Action, pg. 2). The Applicants respectfully disagree. Nonetheless, in order to further the business interests of the Applicants, and without acquiescing to any of the Examiner's arguments or rejections, and solely for the purpose of expediting the patent application process in a manner consistent with the PTO's Patent Business Goals (PBG), and without waiving the right to prosecute the cancelled claims (or similar claims) in the future, the Applicants have amended Claim 1 to recite a method for determining an increased or decreased risk of prostate cancer based on the presence or absence of serum antibodies to HIP1.

The Applicants submit that the specification and the supporting data previously provided by the Applicants (Bradley et al., Cancer Res. 65:4126 [2005]) provide enablement for such embodiments. One skilled in the art (e.g., a clinician trained in screening for prostate cancer such as a primary care physician) would know how to interpret such data. For example, the presence of serum antibodies to HIP1 is indicative of an increased risk of a subject having prostate cancer. If a subject is found to have serum antibodies to HIP1, a decision can be made to pursue further diagnostic testing (e.g., a biopsy). Likewise, the HIP1 marker can be analyzed in combination with other known markers to provide a more thorough risk assessment, upon which a treating physician can use their judgment in selecting appropriate patient care. Such decisions are well within the standard types of decisions that one skilled in the relevant arts

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[1] 65 Fed. Reg. 54603 (Sept., 8, 2000).

would make.

Many common diagnostic assays function in this manner. For example, PSA testing, the current standard of care for prostate cancer screening, is not a definitive diagnostic assay. Subjects having a high PSA reading are at increased risk of having prostate cancer but do not necessarily have prostate cancer. In addition, subjects with low PSA levels can still be found to have cancer. A clinician uses a subject's PSA readings to determine if an individual is at increased risk of prostate cancer. If the subject is found to have an increased risk of prostate cancer based on the PSA screening test, further diagnostic assesement (e.g., biopsy) can be performed to confirm or eliminate a diagnosis of prostate cancer.

Thus, the Examiner's assertion that serum antibodies to HIP1 are not diagnostic because some cancer free patients have positive serum antibodies is not legally relevant to the enablement question. The Applicants' data clearly demonstrates that a higher percentage of patients with prostate cancer have serum antibodies to HIP1 relative to the number of cancer free patients who have serum antibodies to HIP1 (46% versus 27% (See e.g., Bradley et al., Cancer Res. 65:4126 [2005], previously provided by the Applicants). Accordingly, the Applicants submit that the claims are enabled and respectfully request that the rejection be withdrawn.

CONCLUSION

If a telephone interview would aid in the prosecution of this application, the Examiner is encouraged to call the undersigned collect at (618) 218-6900.

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